

REMARKS

Claims 1-71 were originally pending in the present application. Of these, claims 1-38 and 55-71 were identified by the Examiner as drawn to an apparatus for treating gas, classified in class 604, subclass 83, and claims 39-54 were identified as drawn to a method for treating a gas for delivery to an animal, classified in class 604, subclass 500.

By this response, the undersigned attorney of record hereby affirms the provisional election made with traverse to prosecute the invention of claims 1-38 and 55-71 that was made via telephone by previous counsel of record on February 9, 2001. The undersigned attorney of record also acknowledges the withdrawal by the Examiner of claims 39-54 from further consideration. However, claims 13-18 and 24-37 have also been withdrawn from further consideration. Therefore, claims 1-12, 19-23, 38, and 55-71 are currently pending in the present application.

CLAIM REJECTIONS

35 USC § 112

The Examiner has rejected claims 1-31 and 52 as being indefinite. As previously discussed, claims 39-54 have been withdrawn by the Examiner from further consideration, thereby rendering the rejection of claim 52 moot. Moreover, Applicant has cancelled claims 13-18 and 24-37. As a result, only claims 1-12 and 19-23 remain affected by this particular rejection.

The claims comprising the application at issue particularly point out an invention directed to an apparatus for providing gas to body cavities or spaces of a patient during a medical procedure involving the creation of a pneumoperitoneum. As presently claimed, the apparatus is used to humidify, heat and filter the gas prior to delivery to the patient, all of which are now

believed to benefit the patient by decreasing certain post-operative side effects such as pain, hypothermia, and adhesion formation. It was at first assumed, when laparoscopic surgical techniques were first being developed, that the condition of gases used to inflate body cavities were physiologically and pathologically benign. More recently, efforts have been put forth to improve upon the particulate, temperature and/or humidity condition of insufflation gases used to create a pneumoperitoneum.

Claims 1-12 and 19-23 describe the humidification means that may be used with the apparatus, a backup supply container for supplying humidification liquid, and a means for monitoring the humidity level of the conditioned gas. Claims 1-12 have been included in the instant application to clearly describe the humidification means used in the apparatus. As humidification of insufflation gas has become more widely used, particular problems have been perceived with the procedure. For example, the humidification system is ideally set up such that a constant supply of water or other humidifying solution is available to humidify the insufflation gas throughout the entire length of the laparoscopic procedure. However, this seemingly simple statement poses a problem in that it is impossible for a practitioner to know how much gas will actually be used during any procedure. This is largely due to the fact that the practitioner has no control over the amount of gas that is used other than the setting of the flow rate on the insufflator that delivers the gas from the gas source. Further, a number of uncontrollable variables, such leakage of the gas through incisions, changes in surgical technique in response to a patient's anatomy, and/or the occurrence of unexpected complications during the surgery, directly affect the amount of gas that is actually required during the entire duration of a procedure.

Given that it is impossible to predetermine the amount of gas that may be required to complete a procedure, it is likewise impossible to predetermine the amount of water or other humidifying solution that may be required to humidify the gas used throughout the procedure. Thus, the humidity sensing and monitoring means were proposed in the parent application to monitor the relative humidity of the gas and to alert the practitioner to a need for replenishment of the humidification solution supply. See, U.S. Application No. 09/081,186, filed May 19, 1998, "Method and Apparatus for Conditioning Gas for Medical Procedures Having Humidity Monitoring and Recharge Alert," now Patent No. 6,068,609, issued May 30, 2000.

The instant application modifies the apparatus taught by Patent No. 6,068,609 by teaching that the humidity sensing means may be comprised of a humidity sensitive capacitor^(or) resistor. Use of a humidity sensitive resistor in an apparatus for conditioning gas has not been previously described. Where a humidity sensitive resistor is used, an embodiment of the inventive apparatus that is somewhat simplified may be constructed, in that the need for a timer/divider circuit is eliminated (page 19, lines 3-30 and page 20, lines 1-6). Other advantages of the resistive sensor are that such sensor does not require a relatively high frequency square wave signal, it may improve accuracy in certain situations, and the resistive sensor itself can tolerate immersion in water, in the event that the heater/hydrator becomes overfilled (page 20, lines 7-13).

A practitioner may use the backup supply container along with the humidity sensing and monitoring means to extend the supply of humidifying solution readily available during a procedure such that the practitioner does not need to be concerned with running out of solution during a procedure, even if unexpected complications occur that delay completion of the

procedure. In the alternative, use of the backup supply container may eliminate the need for the humidity sensing and monitoring means altogether, thereby simplifying the apparatus.

Thus, Applicant is claiming as the invention an apparatus that will allow a practitioner not only to humidify and/or heat gas to be delivered to a patient during a medical procedure, but also monitor the humidity level of the gas via a humidity sensitive capacitor ~~or~~ resistor element, and have a auxiliary supply of a particular humidifying solution immediately available to ensure that humidification of the gas may be possible throughout an entire procedure.

35 USC § 102

The Examiner has rejected claims 1-5, 12, 13, 19-34, 38, 55-64, 70 and 71 as being anticipated by a patent previously granted to Ott, et al. ("Patent No. 5,411,474"). Patent No. 5,411,474 teaches an apparatus for heating, humidifying and filtering insufflation gas prior to the delivery of the gas to the body cavity of a patient. However, Applicant respectfully disagrees with the Examiner's assessment that Patent No. 5,411,474 teaches the use of capacitors and resistors for humidity sensing means.

Patent No. 5,411,474 does not teach a method for direct sensing or monitoring of humidity levels. Patent No. 5,411,474 specifies that the humidity is not independently controlled (Table 1, column 11, lines 32-33). Instead, the relative humidity is calculated pursuant to the selected temperature of the gas, selected gas flow rate, and porous bed characteristics (Table 1, column 11, lines 14-36).

Clearly, Patent No. 5,411,474 teaches temperature regulation of a gas via "feedback temperature regulation of the heater/humidification chamber," which operates by sensing the temperature of gas exiting the heater/humidification chamber (column 6, lines 64-68). A signal is then sent from the temperature sensing device to a temperature control circuit, which controls an electric resistance heater element that is embedded in the apparatus' humidification bed (column 7, lines 1-5 and column 8, lines 37-40).

Further, Patent No. 5,411,474 specifies that the electrical resistance of the temperature sensing device changes with any detected temperature change in the gas; as the resistance changes the current flow through the temperature sensing device changes (column 7, lines 31-34). It is the change in the electrical resistance that causes the current flow through the temperature sensing device and resistor (column 7, lines 34-35). It is not directly indicated that the temperature sensing means is a temperature sensing capacitor.

The instant application teaches an apparatus that allows a practitioner to directly monitor the relative humidity of gas that is being humidified in preparation for delivery to a patient. With the inventive apparatus, a practitioner can be assured that the gas is at or above a chosen relative humidity before it is delivered to a patient. The practitioner can also be sure that no dry gas is inadvertently delivered to the patient. These characteristics are wholly different from the apparatus taught by Patent No. 5,411,474.

For the foregoing reasons, the Applicant respectfully submits that the apparatus proposed by the instant application is not anticipated by the apparatus taught by Patent No. 5,411,474.

35 USC § 103

The Examiner has rejected claims 8, 10, 11, 13, 14, and 21-24 as being unpatentable over Ott, et al. (Patent No. 5,411,474) in view of Nishino, et al. on obviousness grounds. The Applicant respectfully submits that combination of the humidity sensing device taught by Nishino, et al. with the apparatus taught by Patent No. 5,411,474 was not obvious to one skilled in the art at the time of invention. As previously discussed, at the time Patent No. 5,411,474 and after, studies were being performed to explore the hypothesis that heating and humidification of gas used for insufflation might be effective in reducing such conditions as post-laparoscopic pain and hypothermia. As recognized by Ott, et al. within Patent No. 5,411,474, attention had only just been turned to the possibility that insufflation gases used to create a pneumoperitoneum for laparoscopic surgical procedures should be heated, humidified and filtered (column 1, lines 20-25). There was very little understanding at that time as to what level of relative humidity should

be attained. Moreover, practically no investigation had been done regarding the hypothesis that insufflation gas could be used for the delivery of other therapeutic agents. Thus, at first, there was no need to monitor relative humidity levels of insufflation gas. It was only after further research and development of the gas treatment procedures that such need was realized.

As previously discussed, as the procedures became more widely-practiced, it became clearer that a system needed to be developed to monitor the humidity levels of the gas. In addition, it likewise became clearer that any apparatus used for treatment of insufflation gas should be capable of delivering gas throughout an entire procedure, and should allow the practitioner to treat the gas with agents other than the humidifying solution for delivery to that patient. The external reservoir/bag member has been proposed to address these issues. Inclusion of this element allows a practitioner to have the external reservoir/bag member in order to ensure that a supply of water (or other humidifying solution) would be available for humidification of gas used during an entire procedure. It also enables a practitioner to add an agent to be delivered to the patient at any point during a procedure by connecting the supply bag of the agent to the exterior of the apparatus. Thus, for example, if a practitioner discovers, during the course of a laparoscopic procedure, a previously undetected abscess, an antibiotic solution could be prepared and administered directly to the patient via the gas flow.

In addition, the external reservoir/bag member may simplify the construction of the inventive apparatus. That is, by creating the ability to directly connect the external reservoir/bag member to the apparatus to ensure that ample agent is available for an entire procedure, the need for certain parts, such as humidity and temperature sensing and monitoring features, or the recharge alert, may be eliminated in some embodiments of the apparatus (page 18, lines 1-15).

Finally, with respect to the Examiner's rejection of claims 1-6, 17, 18 and 21-24 as being unpatentable over Ott, et al. in view of Absten (U.S. Patent No. 5,246,419), Applicant respectfully disagrees with the Examiner's assessment of the teachings of Absten, et al. Particularly, Absten, et al. teaches an apparatus for supplying insufflation gas at high flow rates during laparoscopic surgery (column 2, line 43-45). Absten further teaches that one element of

the typical embodiment of said apparatus would include a pressure sensor, *i.e.*, at least one pressure gauge, connected to a microprocessor to automatically reduce the gas flow when a predetermined limit is exceeded (column 5, lines 36-39). Thus, Absten describes an apparatus including a microcontroller used to measure gas pressure.

Absten does not, however, teach the use of the microprocessor for any other purpose other than to measure the pressure of the insufflation gas. Likewise, Absten does not describe with specificity the exact operation of the microprocessor in monitoring the gas pressure levels. It is not stated, nor even suggested by Absten, that it would be within the capability of the microprocessor included in the apparatus to measure the relative humidity of insufflation gas. This is true despite the certain contemplation by Absten, et al., the gas would be humidified before delivery to the patient (column 3, lines 4-6).

For these reasons, there does not appear to be any support for the Examiner's assumption that the microcontroller or microprocessor component of the apparatus taught by Absten, et al., would be capable of monitoring humidity levels of gas.

Double Patenting

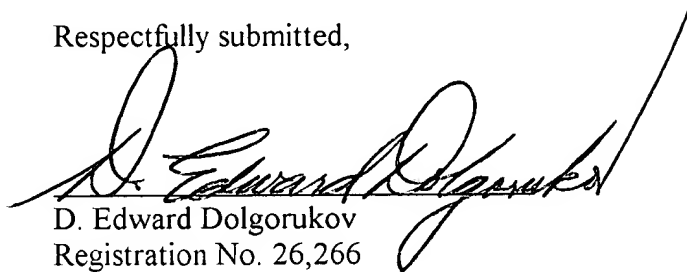
The Examiner has rejected claims 1-6, 17, 18, and 21-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,411,474 and over claims 1-42 of U.S. Patent No. 6,068,609. Applicant has previously discussed how the aspects of the instant application render it substantially dissimilar from the apparatus taught by both Patent No. 5,411,474 and Patent No. 6,068,609.

Patent No 6,068,609 teaches an apparatus that, like that taught by Patent No. 5,411,474, is used to heat, humidify, and filter insufflation gas, but also added the additional aspects of being able to monitor and control the levels of heat and humidity that are added to the gas. In fact, Patent No. 5,411,474 was incorporated in its entirety by reference into Patent No. 6,068,609 (column 1, lines 58-60). Although Patent No. 6,068,609 improves upon the apparatus taught by Patent No. 5,411,474 by adding the capability to monitor the humidification level and recharge

the supply of liquid being used for humidification of the gas, it does not teach treatment of the gas with one or more agents in addition to humidification. It also does not teach an apparatus that may be changed depending upon the identity and number of agents used to treat a gas. The inventive apparatus allows a user to add several agents to a gas, even mid-procedure if necessary, which was heretofore not possible. Compared to prior inventions, which were intended to improve the quality of the gas to decrease deleterious effects on the patient, the instant invention is used to directly deliver agents that will be therapeutically beneficial to the patient.

For the foregoing reasons, the instant application therefore proposes an apparatus that is patentably distinct from either Patent No. 5,411,474 or 6,068,609.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (amended) An apparatus for treating gas prior to the use of the gas in a medical procedure involving a patient, the gas being received into the apparatus from an insufflator which receives gas from a gas source, and the gas exiting the apparatus being in flow communication with a means for delivering the gas to the interior of the patient, wherein the gas is pressure-and volumetric flow rate-controlled by the insufflator, the apparatus comprising:

a) a housing defining a chamber having an entry port and an exit port, the exit port adapted to be in flow communication with the means for delivering and the entry port adapted to be in flow communication with the outlet of the insufflator; and

[c)] b) humidification means disposed within the chamber in the path of travel of the gas through the chamber for humidifying the gas as it travels through the chamber.

71. (amended) The apparatus of claim 70, and further comprising:

a) a temperature sensor disposed in the chamber to sense the temperature of the gas as it exits the chamber; and

b) a control circuit connected to the temperature sensor and to the heating element, and responsive to the temperature sensor to control electrical power to the heating element so as to regulate the amount of heat applied by the heating element to the gas within the chamber, thereby maintaining the gas at a desired temperature or within a desired temperature range.